No. 2013-1286

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ALLERGAN, INC.,
and DUKE UNIVERSITY,

Plaintiffs-Appellees,

and

MURRAY JOHNSTONE, M.D.,

Plaintiff,

v.

ATHENA COSMETICS, INC.,

Defendant-Appellant.

and

PHARMA TECH INTERNATIONAL, INC.,
PRODUCT INNOVATIONS, LLC,
NORTHWEST COSMETIC LABORATORIES, LLC, and
R & G BUSINESS LLC,

Defendants.

Appeal from the United States District Court for the Central District of California in consolidated nos. 07-CV-1316 and 09-CV-0328, Judge James V. Selna.

PRINCIPAL BRIEF FOR ALLERGAN, INC. NON-CONFIDENTIAL VERSION

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CERTIFICATE OF INTEREST

Counsel for plaintiff-appellee Allergan, Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Allergan, Inc.

2. The name of the real party in interest represented by me (if the party named in the caption is not the real party in interest) is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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The material omitted on pages 5, 6, and 37–38 indicates the active ingredients in appellee's product and is taken from documents designated confidential under the parties' protective order; the material omitted on pages 9, 43, and 48 is taken from documents designated confidential under the parties' protective order; the material omitted on lines 3 and 4 of page 48 describes a confidential consumer survey designated highly confidential under the parties' protective order; the material omitted on line 8 of page 48 indicates the dollar sales figures for appellee's product taken from documents designated highly confidential under the parties' protective order.

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, counsel for Allergan states as follows:

(a) There has been one previous appeal to this Court in this case.

(1) Title and number: *Allergan, Inc. v. Athena Cosmetics, Inc.*, 2010-1394

(2) Date of Decision: May 24, 2011

(3) Composition of Panel: Newman, Gajarsa, and Prost, JJ.

(4) Federal Reporter Citation: 640 F.3d 1377

(b) Allergan is aware of no other case that will be directly affected by the Court's decision in this case.

INTRODUCTION

In a thorough and well-reasoned decision, the district court granted summary judgment to appellee Allergan, Inc. on its unfair competition claim against appellant Athena Cosmetics, Inc. After considering all the relevant factors required by *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006), the court then permanently enjoined Athena's unlawful conduct. This Court should affirm.

For years, Athena has cut corners, building a multi-million dollar business by skirting the law. Unlike lawful pharmaceutical companies—including Allergan—that spend billions of dollars on research, development, and clinical testing in order to obtain regulatory approval for their products pursuant to strict requirements of safety and efficacy, Athena decided to simply market and sell an unapproved drug to the masses, confident that the agencies tasked with oversight—including the California Department of Health Services and the United States Food and Drug Administration—would be too overburdened to take action.

On summary judgment, Allergan presented the district court with a mountain of evidence showing Athena's objective intent that its eyelash growth product, "RevitaLash," be used to grow human hair. Under California's Health and Safety Code, this evidence compelled, or at least permitted, the district court's conclusion that RevitaLash is a drug. Similarly, the court correctly concluded that because Athena never sought or received regulatory approval for RevitaLash, it is neces-

sarily an unapproved new drug being sold in violation of state law. Finally, after being presented with evidence regarding the lost sales and market share Allergan suffered as a result of Athena's illegal activity, as well as the practical and functional scope of an appropriate injunction, the district court entered a nationwide injunction, enjoining Athena from selling its unapproved new drug.

On appeal, Athena's principal argument is that Allergan's claim under the California Unfair Competition Law (UCL) is preempted by federal law. The Federal Food, Drug, and Cosmetic Act (FDCA), however, contains a savings clause that preserves state-law claims such as this. Moreover, there is no actual conflict between the FDCA and its implementing regulations and California's parallel regime, and thus no implied preemption. Athena also complains that the district court should have taken a more restrictive view of the evidentiary record, and that Athena's self-selected facts are not sufficient to prove that RevitaLash is a drug. But courts may consider all available indicia of objective intent in deciding whether a product is a drug, and Athena has shown no error in the district court's summary judgment determination on the entire record. Finally, Athena maintains that the district court abused its discretion in entering a nationwide injunction. The district court, however, made specific findings that Athena's continued unlawful conduct will cause irreparable harm to Allergan, its direct competitor, and it had ample equitable authority to remedy Athena's adjudicated violation of California law.

STATEMENT OF FACTS

1. Allergan develops and commercializes innovative pharmaceuticals, biologics, and medical devices. A1144–45. A primary focus for over ten years has been the investigation and development of potential beneficial uses for the prostaglandin analog Bimatoprost. A1145–46. Allergan researchers discovered that Bimatoprost grows hair, including eyelashes, and claimed this invention in one of the three Allergan patents formerly at issue in this case, United States Patent No. 7,351,404 (the '404 patent). A0373–74, A3642–54. Allergan markets and sells a prostaglandin eyelash growth drug under the brand name Latisse, as a prescription treatment for hypotrichosis. A1144–45.[1]

In 2008, Allergan submitted an application to the Food and Drug Administration (FDA) for the approval of Bimatoprost for growing eyelashes. A1144, A1170–1242. Such approval is required as a matter of federal law because the FDA has determined that *all* hair growth products for external use are "new drugs" requiring FDA premarket approval. 21 C.F.R. § 310.527(b) ("Any OTC drug product that is labeled, represented, or promoted for external use as a hair grower ... is regarded as a new drug ... for which an approved new drug application ... is

[1] Duke University owns a patent previously at issue in the case (United States Patent No. 7,388,029), which Allergan sought to enforce as the exclusive licensee. A0365, A3695–722.

required"); *United States v. Kasz Enters., Inc*., 855 F. Supp. 534, 541 (D.R.I. 1994) ("all OTC hair growth ... products must ... [have] an approved new drug application[] before they can be marketed"); *id.* at 541 n.5 (discussing regulatory history); 54 Fed. Reg. 28,772 (July 7, 1989). California law has adopted the same requirement. Cal. Health and Safety Code § 110110.

In support of its FDA application, Allergan submitted the results of robust safety and efficacy studies derived from years of clinical research involving thousands of subjects. A1145–54, A1169–1243, A1254–69, A1276–1449. Based on its excellent safety record and proof that Bimatoprost grows eyelashes, the FDA approved Allergan's application for Latisse in December 2008. A1144, A1268.

Though clinically proven to safely and effectively grow eyelashes, and even though it was approved by the FDA over four years ago, Latisse is still available only by prescription. A1144–45. The FDA also requires Allergan to include substantial safety warnings on all Latisse labeling and in its marketing. A1244–53, A1267–68. Significantly, Latisse remains the only prostaglandin drug approved in the United States for growing eyelashes. A1144.

2. Athena also markets and sells a line of prostaglandin hair-growth products including RevitaBrow, Hair by RevitaLash, and, until enjoined by the district court, RevitaLash. A0710–18. Athena marketed and sold RevitaLash—and continues to market and sell its other products—on its website and through an exten-

sive network of resellers and affiliates. A0741–43; *see also* A0750–917, A0925–26, A1092–1102. Athena has neither sought nor obtained regulatory approval, and does not require a prescription for its products. A0725–26.

Athena marketed its first eyelash growth product under the name RevitaLashMD. Like Latisse, RevitaLashMD contained the active ingredient Bimatoprost, which Athena labeled "Formula LashGro (proprietary formulation)" on its packaging. A0919; *see also* A0733. Athena promised consumers that RevitaLashMD would give them "Longer, Thicker, Fuller Lashes in 60 Days Guaranteed." A0735–38, A0760.

Since the 2006 introduction of RevitaLashMD, Athena has reformulated RevitaLash—by swapping prostaglandin analogs—three times. Athena first replaced Bimatoprost with [redacted] in November 2007, in response to the FDA's seizure of a competing eyelash growth product sold by a former defendant in this case. A0680–81, A0689; *see also* A0710–17, A0727, A1033–34. Athena's next iteration included the prostaglandin analog [redacted]. A01539; *see also* A0710–17. Athena adopted *this* reformulation following the district court's claim construction ruling, which established that Athena's prior formulation fell within the scope of Allergan's '404 patent. *See* A3554–602. Though some of Athena's marketing referenced this new formulation as "RevitaLash Enhanced," Athena's sales representatives, consumers, and much

of Athena's website continued to call the product by its established name, "RevitaLash." *E.g.*, A0862–63, A0951, A0982–86. Athena reformulated RevitaLash *yet again* in 2011 by replacing [redacted] with the prostaglandin analog [redacted]. A0710–17, A01539–40. This reformulation followed an FDA warning letter to another former defendant regarding a similar product, which, the FDA stated, was an illegal unapproved new drug. A1036–38.

Athena's testing of its latest RevitaLash formulation confirmed that it effectively grew eyelashes "within just 3 weeks." A1099. Athena even filed a patent application disclosing the synthesis of the new compound and stating that "[r]epeated application for consecutive days, weeks or months" "will … stimulate or promote the growth of eyelashes" when "applied at the base of any eyelid adjacent to or where hair grows from the follicles (e.g., along the lashline)" or to "the eyelashes themselves." A0998, A1542. Not coincidentally, the RevitaLash instructions continued to teach the same method of application. *See* A0988 ("Once-a-day, at bedtime: apply a thin line of RevitaLash to the base of your lashes"); *see also* A0838. Athena made commercial use of all these statements. *See*, *e.g.*, A0750, A0769, A0785, A0799–800, A0841, A0850, A0862–63, A0871, A0945, A0988, A1025, A1093–99.

Although Athena opportunistically calls its newest formulation "RLA" on appeal (AOB4), that term has never been communicated to consumers, and is an obvious after-the-fact attempt to distinguish its latest RevitaLash formulation. Athena has always marketed the product as "RevitaLash Advanced" or, more commonly, "RevitaLash." *E.g.*, A0820–30, A0832–44, A0871, A0877–81, A0926, A2736.

And although Athena now states that it stopped marketing RevitaLash as an eyelash growth product in June 2007 (AOB44), the record shows that Athena has always marketed RevitaLash as a revolutionary product that grows eyelashes longer, thicker, and fuller after just a few short weeks of nighttime application.

For example, since 2007, Athena and its resellers have consistently advertised RevitaLash as physician formulated to regrow eyelashes lost as a result of chemotherapy. *See*, *e.g.*, A0820–21 (June 2011) ("in just a matter of a few short weeks … her eyelashes started to become fuller and thicker ... and lo[] and behold the birth of RevitaLash"), A0875 (July 2011). Athena and its resellers also continued to publish a panoply of before-and-after photos demonstrating eyelash growth (A0743, A0752–58, A0789, A0941, A0960), as well as testimonials and celebrity endorsements proclaiming the product's ability to grow lashes, *e.g.*, A0778 (November 2009) ("It's pricey ... but it really works .... Daddy Long Leg size eye lashes."), A0780, A0787, A0859–60, A0862–63 (June 2011) ("I noticed positive

results [in] about 3 weeks.... I now have 'bump your sunglasses' lashes!"). A particularly cheeky 2011 campaign from an international affiliate (published online in the United States) featured "the Great RevitaLash/Chia Pet Grow-off ... which … pit[ted] a lab approved lash growth formula [RevitaLash] against an adorable ceramic hippo covered in seeds." A0938.

Athena's sales representatives also continued to promote RevitaLash for eyelash growth in direct communications with resellers and consumers in the years following 2007. *See*, *e.g.*, A0767 (October 2008) ("I represent RevitaLash, an amazing eyelash condition[er] that actually gives you longer, thicker and fuller eyelashes!"), A0776 (July 2009) ("Just checking in to see how everybody's eyelashes are growing???"), A0865 (August 2011) ("My eyelashes now touch the inside of my glasses and are just so lush"). For example, during a June 2011 "webinar," Athena's sales representatives explained that "Many customers like to go on a maintenance program [with RevitaLash] ... after [they] have the desired length" and that "itchiness" following application is due to "RevitaLash … saying to your eyelashes, 'Wake up …. Start to become fuller and thicker and longer.'" A0822, A0824. Athena has even provided its sales representatives with articles proclaiming the benefits of "eyelash growth products" to use in promoting RevitaLash. A0799–800 ("[For use] in your bag of tools! Happy Selling!").

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Similarly, Athena and its resellers consistently marketed RevitaLash as the over-the-counter alternative following the FDA's approval of Latisse in December 2008. A0887 ([redacted]), A0825 ("[I]t depends on the convenience that your customer wants. They can certainly purchase RevitaLash from you or they need to go to the physician to receive a prescription for [Latisse]."), A0869 ("Unlike other options that require a prescription, RevitaLash Advanced is affordable and offers very similar results"). Athena even sought to commission a "clinical trial" involving "[redacted]" to compare the growth effects of Latisse and RevitaLash in 2009. A0892 ("[redacted]"); *see also* A0895 ("[redacted]"), A0898 (comparing growth after four weeks in a patient who tried RevitaLash and Latisse on the right and left eyelashes, respectively).

RevitaLash has never been vetted or approved by the California Department of Health Services, the FDA, or any other regulatory body. A0725–26. In fact, Athena admits that it has failed even to *seek* such regulatory approval or conduct

the clinical testing necessary to support an application. A1540–42; *see also* A1039–99.

3. Allergan's original complaint alleged infringement of United States Patent No. 6,262,105 ("Method of Enhancing Hair Growth") against Athena and several other defendants based on their manufacture, promotion, and sale of eyelash growth products containing certain prostaglandin analogs. A0225–32. Allergan later amended the complaint to include additional defendants and to assert infringement of the subsequently issued '404 patent (among others). A0233–51.

Allergan amended its complaint in August 2009 to assert a claim under California's Unfair Competition Law, based on the manufacture, marketing, and sale of unapproved eyelash growth products by Athena and other defendants. A3390–407. California's UCL provides a right of action to enjoin conduct that is "unlawful" (Cal. Bus. & Prof. Code § 17203), which Allergan asserted here based on defendants' violation of the California Health and Safety Code. Significantly, Allergan did not allege—and has never alleged—any specific violations of the FDCA, though defendants certainly violated many FDCA provisions as well.

The district court initially granted judgment against Allergan on the ground that it lacked standing to sue Athena and other competitors under the UCL. A3603–14. This Court reversed, relying on several recent California Supreme Court decisions to hold that "there are 'innumerable ways' to show economic inju-

ry from unfair competition" (*Allergan, Inc. v. Athena Cosmetics, Inc.*, 640 F.3d 1377, 1388 (Fed. Cir. 2011) (citing *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 323–24 (2010))), that "Allergan has plainly alleged an economic injury that was the result of an unfair business practice" (*id.* at 1382), "and therefore Allergan has standing to pursue its claim for [injunctive] relief under the UCL," *id.* (citing *Kwikset*, 51 Cal. 4th at 335; *Clayworth v. Pfizer, Inc.*, 49 Cal. 4th 758, 788–89 (2010)).

On remand, Allergan filed a consolidated amended complaint, asserting additional false advertising claims against Athena based in part on its promotion of RevitaLash as comparatively safer than Latisse because it is sold without a prescription. A0360–84. After discovery, Allergan moved for summary judgment against Athena on its UCL claim. Allergan argued that RevitaLash is a "drug" pursuant to California's Health and Safety Code because it is intended to grow eyelashes, and that Athena's marketing and sale of RevitaLash without regulatory approval necessarily violated a host of Health and Safety Code provisions. A0589–620.

The district court granted summary judgment to Allergan. The court held that in determining whether RevitaLash was a "drug," it may examine "any … relevant source" in determining Athena's objective intent with respect to RevitaLash, rejecting Athena's arguments for a more restrictive inquiry. A0030–31. And

based on a voluminous summary judgment record, the court concluded "that the uncontroverted facts establish as a matter of law that RevitaLash Advanced [and all previous iterations] are objectively intended to grow eyelashes" rendering them "drugs under the FDCA and the Cal. Health and Safety Code." A0034. Because RevitaLash is a drug for which Athena has not received federal or state approval, its continued marketing and sale constituted a violation of California law. *See*, *e.g.*, *In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1095 (2009).

Allergan then moved for a permanent injunction to enforce its successfully adjudicated UCL claim. A2495–526. In support of its motion, Allergan submitted evidence that, notwithstanding a declaration from Athena's President and CEO stating "Athena [had] voluntarily discontinued all sales and promotion of … RevitaLash[] in the United States" (A2238), Athena continued to sell RevitaLash to consumers in California directly from its website, as did its many online and brick-and-mortar resellers. A2728–84. Athena and its resellers also continued to market RevitaLash as an eyelash growth drug, and even sought to expand the customer base further by marketing another product, RevitaBrow, as equivalent to RevitaLash. A2732–33. One reseller represented to end users that it had received specific instructions from Athena that RevitaBrow was "approved" for use on eyelashes "as a replacement for RevitaLash." A2732.

The court granted Allergan's motion and enjoined Athena from manufacturing, marketing, or selling its unlawful eyelash growth products anywhere within the United States, given "the nationwide demand cultivated by Defendants." A0040–55. The patent and false advertising claims against Athena were dismissed without prejudice pursuant to the parties' agreement following entry of the injunction. A3829–31. Only the UCL claim remains on appeal.

SUMMARY OF ARGUMENT

I. Allergan's UCL claim is not preempted by federal law because the FDCA specifically allows states to enact and enforce parallel state laws. Moreover, because the relevant provisions of the California Health and Safety Code parallel federal law, enforcement of those provisions through the UCL (as expressly permitted by state law) does not conflict with or otherwise present an obstacle to federal law. It is not impossible for Athena to comply with both state and federal law.

II. Athena argues on appeal that the district court should have limited its analysis to only Athena's most current marketing materials in determining whether RevitaLash was a drug requiring regulatory approval. But Athena cites no authority for this purported evidentiary limitation, and the case law and regulatory guidance are entirely to the contrary. The district court properly considered all the evidence—both historic and current—and reached the correct decision that RevitaLash is a drug and that Allergan was therefore entitled to summary judgment.

III. The district court did not abuse its discretion in enjoining Athena's unlawful conduct. The court properly applied the traditional equitable factors and, after making specific factual findings that Athena's unlawful conduct was causing irreparable harm to Allergan, issued a nationwide injunction in order to prevent that harm and protect the public interest.

The judgment entered by the district court should be affirmed.

STANDARD OF REVIEW

This Court applies "the law of the regional circuit to which district court appeals normally lie, unless the issue pertains to or is unique to patent law." *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1363 (Fed. Cir. 2004). Because Athena's appeal does not touch on any issues related to patent law, Ninth Circuit law controls.

"A district court's decision regarding preemption is reviewed de novo." *Californians for Safe & Competitive Dump Truck Transp. v. Mendonca*, 152 F.3d 1184, 1186 (9th Cir. 1998). A district court's denial of a request to refer a case to an agency under the primary jurisdiction doctrine is reviewed for abuse of discretion. *GCB Commc'ns, Inc. v. U.S. S. Commc'ns, Inc.*, 650 F.3d 1257, 1262 (9th Cir. 2011). The district court's grant of summary judgment is reviewed de novo, and this Court "may affirm the district court's holding on any ground raised below and fairly supported by the record." *Columbia Pictures Indus., Inc. v. Fung*, 710

F.3d 1020, 1030 (9th Cir. 2013). The district court's decisions on relevance and other evidentiary matters are reviewed for abuse of discretion. *Range Rd. Music, Inc. v. E. Coast Foods, Inc.*, 668 F.3d 1148, 1152 (9th Cir. 2012). "As to the permanent injunction, [the Court] review[s] the legal conclusions de novo, the factual findings for clear error, and the decision to grant a permanent injunction, as well as its scope, for an abuse of discretion." *Columbia Pictures*, 710 F.3d at 1030.

ARGUMENT

Athena requests reversal on the grounds that (I) Allergan's state-law claim is preempted by federal law, (II) the district court's summary judgment ruling was not supported by the evidentiary record, and (III) the injunction was an abuse of discretion. Athena is wrong on all counts.

I. Allergan's California Unfair Competition Law Claim Is Not Preempted

Congress specifically allowed states to enact laws parallel to the FDCA. *See* 76 Stat. 793, § 202; A3845. Accordingly, California's Health and Safety Code—which imposes obligations parallel to those under the FDCA—is not preempted. And because there are no material differences between the pertinent standards under the two laws, there is no conflict between state and federal law. Thus, the district court properly held that Allergan's claim was not preempted.

A. The FDCA Expressly Permits Concurrent State Regulation

Congress's express statement in the FDCA that states may enact and enforce parallel state laws disposes of Athena's claim that the pertinent provisions of California's Health and Safety Code (which are commonly known collectively as the Sherman Law) are preempted.

The controlling question in determining whether a statute is preempted is: "Did Congress, in enacting the Federal Statute, intend to exercise its constitutionally delegated authority to set aside the laws of a State?" *Barnett Bank, N.A. v. Nelson*, 517 U.S. 25, 30 (1996). In answering this question, courts begin with an assumption *against* preemption. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) ("we start with the assumption that historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress") (citation omitted). Only when "Congress has 'unmistakably ... ordained'… that its enactments alone are to regulate a part of commerce [must] state laws regulating that aspect of commerce fall." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)).

Before the enactment of the FDCA's precursor—the Pure Food and Drug Act of 1906—the States provided the primary means of regulatory control over the labeling of foods and drugs. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). Reflect-

ing the historic importance of traditional state-law tort remedies, Congress left these tort remedies in place when it enacted the Pure Food and Drug Act of 1906. *Id*. (the 1906 Act "prohibited the manufacture or interstate shipment of adulterated or misbranded drugs [and] supplemented the protection for consumers already provided by state regulation and common-law liability"). "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

In enacting the FDCA, Congress "t[ook] care to preserve state law" in this area by adding a "savings clause" in the 1962 amendments to the FDCA. *Wyeth*, 555 U.S. at 566–67. This savings clause provides that "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law ... unless there is a direct and positive conflict between such amendments and such provision of State law." 76 Stat. 739, § 202; A3845; *see Mut. Pharm. Co. v. Bartlett*, 2013 WL 3155230, at *10 (U.S. June 24, 2013) ("When federal law *forbids* an action that state law *requires*, the state law is without effect") (quotation omitted) (emphases added). Athena completely ignores this provision of the FDCA.

Later amendments to the FDCA have scaled back this savings clause as it pertains to certain narrow topics inapplicable here, including medical devices, ra-

diation emission, and non-prescription drugs, by adding express preemption provisions. *See* 21 U.S.C. § 360k(a) (medical devices); *id* § 360ss (radiation emissions); *id.* § 379r (non-prescription drugs); *id.* § 379s (cosmetics). But Congress has "declined to enact such a provision for prescription drugs." *Wyeth*, 555 U.S. at 567; *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008) (Congress did not "appl[y] the pre-emption clause to the entire FDCA, … but instead wrote a pre-emption clause that applies only to medical devices").

California, like many states, has adopted the Uniform FD&C Act (*see* Cal. Health & Safety Code § 111550), which in many respects mirrors the FDCA. With respect to the regulation of prescription drugs, and other subjects, California's Sherman Law imposes requirements that are parallel to those imposed under the FDCA. *Farm Raised Salmon Cases*, 42 Cal. 4th at 1095 ("the Sherman Law imposes obligations identical to those imposed by the FDCA").

Allergan's claim—as pleaded in the complaint and established on summary judgment—is that Athena has violated California Health and Safety Code sections 111550, 110398, and 111440 by "marketing, selling, and distributing [its] hair and/or eyelash growth products without [a New Drug] application approved by the FDA or the California State Department of Health Services." A0375–77. These underlying Health and Safety Code violations serve as the predicate violations for a claim under California's UCL, which prohibits "any unlawful, unfair or

fraudulent business act or practice, and unfair, deceptive, untrue or misleading advertising ...." Cal. Bus. & Prof. Code § 17200. "By proscribing any unlawful business practice, section 17200 borrows violations of other laws and treats them as unlawful practices that the unfair competition law makes independently actionable." *Cel-Tech Commc'ns Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 180 (1999) (quotations and citations omitted).

Athena repeatedly insists that Allergan sought to enforce the FDCA. *E.g.*, AOB5–6, 27, 30. That is, of course, wrong: Allergan sued *only* under state law (the UCL) to remedy violations of state law (the Sherman Law). Thus, many of the authorities on which Athena relies the most heavily are inapposite. For example, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010), as Athena admits (AOB31 n.11), primarily involved Lanham Act claims which were premised on violations of the FDCA—*not* California's Health and Safety Code. In the rare instances where Athena addresses California, it argues that "the state law requirements at issue" in Allergan's claims "did not merely *mirror* those [requirements] of the FDCA—they *were themselves* FDCA requirements." AOB35–36. That too is wrong: States frequently adopt the language of federal requirements, but that does not make state law the same as federal law. *Cf. Smith v. Bayer Corp.*, 131 S. Ct. 2368, 2377 (2011) ("Federal and state courts, after all, can and do apply identically worded procedural provisions in widely varying ways").

Although California makes it lawful to sell a new drug if a new drug application has been approved under section 505 of the FDCA (*see* Cal. Health & Safety Code § 111550(a)), it *also* makes the sale of a new drug lawful if the California Department of Health Services has approved a new drug application, *see id.* at § 111550(b). The requirements are parallel but not identical; obtaining regulatory approval from the FDA is *not* required in order to comply with this provision of the Health and Safety Code. The district court thus held that Athena failed to comply with California's Health and Safety Code for failing to obtain regulatory approval from *either* the California Department of Health Services *or* the FDA before selling RevitaLash. *See* A0034.[2]

Athena argues that Allergan's claims "necessarily involve reference to and interpretation of the relevant FDCA statutes and regulations." AOB36 (quotations and citations omitted). This is not a basis for preemption. There is no doubt that because the Sherman Law adopts by incorporation FDCA standards, authorities interpreting the FDCA may be highly instructive. *See*, *e.g.*, *United States v. Johnson*

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[2] Contrary to Athena's assertion that no procedure exists allowing the submission of a new drug application to the California regulatory body, sections 111550 and 111555 of the Health and Safety Code address the filing and review of such applications. Therefore, Athena would be wrong to argue that the Sherman Law is preempted because it requires Athena to withhold a lawful product from the market. *Cf. Bartlett*, 2013 WL 3155230, at *10.

Controls, Inc., 457 F.3d 1009, 1021 (9th Cir. 2006) ("Where the wording and objectives of a California statute are similar to the wording and objectives of a federal statute, California courts look to interpretations of the federal statute for guidance in interpreting the state statute") (citations omitted). That does not, however, make state law federal.

The California Supreme Court's decision in *Farm Raised Salmon* is indistinguishable from the present case—it involved the exact same type of claim (under the UCL for violation of the California Health and Safety Code), and rejected precisely the preemption arguments Athena raises here. 42 Cal. 4th at 1094–95. It is immaterial that *Farm Raised Salmon* involved deceptive marketing practices (*see* AOB37–40), because California's UCL does not distinguish among claims that are "unlawful." *Kwikset*, 51 Cal. 4th at 320 ("The UCL prohibits …'*any* unlawful … act'") (quoting Cal. Bus. & Prof. Code § 17200) (emphasis added).

Contrary to Athena's assertion, the *Farm Raised Salmon* plaintiffs' UCL claim was not merely about "a seller's general duty not to make fraudulent statements about its merchandise" (AOB38); rather, it involved—as does Allergan's claim—a pure statutory violation. Athena claims that in *Farm Raised Salmon*, the court merely *applied* regulations, while in the instant case, the district court was required to *interpret* regulations. AOB39. There is no relevant distinction between "application" and "interpretation" under these circumstances. *Cf. United*

States v. Mead Corp., 533 U.S. 218, 227 (2001) (recognizing that "agencies charged with applying a statute necessarily make all sorts of interpretive choices"); *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 363 (2d Cir. 2010) ("plaintiffs' distinction between … 'interpretation' and an 'application' is untenable and without support in our case law").

Although not binding on this Court, the thorough and well-reasoned decision in *Farm Raised Salmon* is of significant persuasive value here. The California Supreme Court considered many sources of evidence demonstrating Congress's preemptive intent, scoured the legislative history of the FDCA, considered the opinion of experts in the field, and ultimately determined that Congress did not intend to preempt claims like Allergan's. 42 Cal. 4th at 1090–99. Other federal courts have already followed *Farm Raised Salmon*. *See*, *e.g.*, *Delacruz v. Cytosport, Inc.*, 2012 WL 2563857, at *7 (N.D. Cal. June 28, 2012); *Zeisel v. Diamond Foods, Inc.*, 2010 WL 9509506, at *3 (N.D. Cal. Sept. 3, 2010); *Hansen Bev. Co. v. Innovation Ventures, LLC*, 2009 WL 6597891, at *3, *9–10 (S.D. Cal. Dec. 23, 2009). Athena's allegedly contrary authority (*see* AOB35–37) does not, in fact, represent any conflict among the district courts on this question.[3]

[3] *Goldsmith v. Allergan, Inc.*, 2011 WL 147714 (C.D. Cal. Jan. 13, 2011), is irrelevant because it involved a UCL claim premised on a violation of the

This Court could not rule for Athena on the preemption question in this case without creating a direct conflict with the California Supreme Court on an identical question of law. Affirmance, by contrast, would not only secure uniformity of decision, but also ensure the correct result as a matter of federal law.

B. There Is No Actual Conflict Between the FDCA and California's Health and Safety Code

To establish that a state statute is preempted, Athena must show that "compliance with both federal and state regulations is a physical impossibility" or that state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hillman v. Maretta*, 133 S. Ct. 1943, 1949 (2013) (citations omitted). No such conflict exists here.

"When faced with a potential conflict" between federal and state law, "[c]ourts try to give as much effect to both statutes as possible." *POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1175 (9th Cir. 2012) (quotations and citation omitted). This means that, to the greatest extent possible, this Court should

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FDCA—not a claim of unlawfulness predicated on violation of California's Health and Safety Code. *Id.* at *2–3, *7–8. Athena's other authorities, *Animal Legal Defense Fund v. Provimi Veal Corp.*, 626 F. Supp. 278 (D. Mass 1986), and *Fraker v. KFC Corp.*, 2007 WL 1296571 (S.D. Cal. Apr. 30, 2007), predate *Farm Raised Salmon*, as well as the Supreme Court's *Wyeth* decision, which clarified that the FDCA did not intend to disrupt state tort laws. Moreover, the plaintiff in *Fraker* brought claims directly based on the FDCA. *See Hansen*, 2009 WL 6597891, at *11.

harmonize California's Health and Safety Code with the FDCA, particularly where, as here, "a finding of preemption will foreclose a remedy that was traditionally available and for which federal law provides no substitute." *Perry v. Novartis Pharms. Corp.*, 456 F. Supp. 2d 678, 684 (E.D. Pa. 2006); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 488–89 (1996) ("[Defendant's] sweeping interpretation of the [FDCA] would require far greater interference with state legal remedies, producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of remedy for the [plaintiff's] alleged injuries").

Athena insists that "[t]he leading case on implied preemption under the FDCA is *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001)." AOB25. Athena claims that the Court in *Buckman* "laid down the applicable test" to determine whether a state-law claim involving the FDCA was impliedly preempted: "[W]here no 'traditional state law tort principle' is involved, and the plaintiff's state-law claim 'exist[s] solely by virtue of' the defendant's alleged FDCA violations, the claim is preempted." AOB26–27. Athena is incorrect; *Buckman* is inapposite.

Buckman involved medical devices (531 U.S. at 343), and the FDCA contains an express preemption provision relating to those devices' regulation, evidencing Congressional intent to permit less state involvement in this area, *see* 21 U.S.C. § 360k(a). That provision does not apply here.

Moreover, and as Athena recognizes in its brief (AOB2), *Buckman* involved claims based wholly on dealings with the FDA. *See* 531 U.S. at 343. Indeed, the plaintiffs' claims in *Buckman* were premised on allegations that drug manufacturers deceived the FDA in order to obtain approval for their medical device. *Id.* ("Plaintiffs say petitioner made fraudulent representations to the [FDA] in the course of obtaining approval to market [its orthopedic bone] screws"). The plaintiffs' "fraud claims exist[ed] *solely* by virtue of the FDCA disclosure claims." *Id.* at 353 (emphasis added). Allergan's claim, by contrast, is not based wholly, or even in part, on the FDCA, but is based on California's Health and Safety Code.

Courts across the country have properly limited the reasoning in *Buckman* to claims that are necessarily dependent on—and which could not survive without—federal law, including claims for defrauding a federal agency. For example, in *Perez v. Nidek*, 711 F.3d 1109 (9th Cir. 2013), the plaintiff's fraud-by-omission claim was preempted because the claim existed "solely by virtue of the FDCA ...." *Id.* at 1119; *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 176–77 (1st Cir. 2009) ("*Buckman* addressed a more narrow scenario: the plaintiffs in that case employed a 'fraud-on-the-agency' theory to attempt to create derivative standing for their own suits"); *Kubicki v. Medtronic*, 2013 WL 1739580, at *11 (D.D.C. Mar. 21, 2013) ("Plaintiffs' claims ... unlike those in *Buckman*, are

state claims based upon Defendants' alleged violation of common law and statutory duties to Plaintiffs—not fraud on the FDA").

The Supreme Court's 2009 *Wyeth* decision articulates the controlling preemption test here: Where simultaneous compliance with both the state and federal law is possible, and the state law does not pose an obstacle to the realization of federal goals, the state law is not preempted. 555 U.S. at 589–90; *see also Fla. Lime*, 373 U.S. at 143 (state law would be preempted "if, for example, the federal orders forbade the picking and marketing of any avocado testing more than 7% oil, while the California test excluded from the State any avocado measuring less than 8% oil content"); *Bartlett*, 2013 WL 3155230, at *6 ("state law is impliedly preempted where it is *impossible* for a private party to comply with both state and federal requirements") (citation omitted).

Athena does not identify any way in which it would be impossible for it to comply with both the California Health & Safety Code and the FDCA. Indeed, as discussed above, the state statute's requirements at issue here precisely parallel those imposed under the FDCA. *See supra* pp. 18–20; *see also Farm Raised Salmon*, 42 Cal. 4th at 1095. Far from impossible, Athena could (and should) comply with both regimes, which are congruent, by seeking regulatory approval for its products, as Allergan has done. Instead it has elected to comply with neither.

Where compliance with both the state and federal law is *possible*, the state law will be impliedly preempted only if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). "To determine whether a state law conflicts with Congress' purpose and objectives, [courts] must first ascertain the nature of the federal interest," then determine whether the state law is antithetical to those interests. *Hillman*, 133 S. Ct. at 1950 (citing *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000)).

Congress's purpose in enacting the FDCA was to advance consumer safety (*Wyeth*, 555 U.S. at 574)—to "protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696 (1948). California's Health and Safety Code does not detract from or frustrate that purpose; indeed, California law *furthers* that purpose. *See* Cal. Health & Safety Code § 111550(b)(1) (requiring that new drugs be "safe for use"). California law is therefore not preempted.

As the Supreme Court has recognized, the "FDA has limited resources to monitor the 11,000 drugs on the market." *Wyeth*, 555 U.S. at 578; *see also* Institute of Medicine of the National Academies, The Future of Drug Safety: Promoting and Protecting, the Health of the Public 193 (2007) (the FDA "lacks the resources to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future"). And although "Congress enacted the FDCA

to bolster consumer protection against harmful products," it "did not provide a federal remedy for consumers ... [because e]vidently it determined that widely available state rights of action provided appropriate relief for injured consumers." *Wyeth*, 555 U.S. at 574. California law also affords a right of action enforceable by injured competitors, and nothing in the FDCA preempts Allergan's claim under that provision.

C. The District Court Properly Retained Jurisdiction

In the alternative to its preemption argument, Athena argues that the district court should have deferred to the FDA under the prudential doctrine of primary jurisdiction. AOB41. Such deference is warranted where "a court determines that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance with regulatory authority over the relevant industry, rather than by the judicial branch." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008).

Only one factor of the primary jurisdiction analysis—whether the issues in the case require "expertise or uniformity of administration" (*Clark*, 523 F.3d at 1115)—was disputed below. The district court correctly determined that "[a]ny level of expertise" required to determine Athena's "intended use" for its product "is not the type that is beyond the Court or more likely found in an administrative agency." A0014. Allergan's claim did not require understanding of complicated

or technical issues. A0012–14; *see also POM Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1123 (C.D. Cal. 2009), *overruled in part on other grounds by POM Wonderful LLC*, 679 F.3d at 1178; *Farm Raised Salmon*, 42 Cal. 4th at 4. And given the individualized nature of the "intended use" inquiry, the district court correctly concluded that "[a] highly contextual determination for one set of products is unlikely to create uniformity in administration problems just from the fact that a court makes a determination and an agency may make others." A0015. Athena could not "supply any definite time horizon for when agency determination would occur or if it would ever occur." *Id*.

The district court's refusal to stay the case under the primary jurisdiction doctrine was not an abuse of discretion.

II. The District Court Properly Granted Summary Judgment on Allergan's UCL Claim

Allergan established below that there was no genuine issue of material fact and therefore that it was entitled to summary judgment on its UCL claim. Athena's challenge to the district court's decision misstates the law and ignores the wealth of evidence before the district court showing that RevitaLash is a "drug" under California law, and therefore required regulatory approval. This Court should affirm.

A. The District Court Properly Considered All Relevant Evidence in Determining That RevitaLash Is a Drug

Any product "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body of human beings" is a "drug" under California (and federal) law. Cal. Health & Safety Code § 109925(b), (c); *see also* 21 U.S.C. § 321(g)(1)(B), (C). Indeed, *any* product intended to grow hair is considered a drug and a "new drug" requiring regulatory approval under California (and federal) law. 21 C.F.R. § 310.527(b); 54 Fed. Reg. 28,772 (July 7, 1989); Cal. Health & Safety Code § 110110.

Nothing in the statute limits the evidence courts may properly consider when determining whether a given product is a "drug," *i.e.*, whether a product is intended to "grow hair." To the contrary, "[t]he drug definition is to be given a liberal interpretation in light of the remedial purposes of the legislation." *Nat'l Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 336 (2d Cir. 1977) (citing *United States v. An Article of Drug ... Bacto-Unidisk*, 394 U.S. 784, 792, 798 (1969)).[4]

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[4] Further, the terms "drug" and "cosmetic," as used in the statute are not mutually exclusive; a product may be both a cosmetic and a drug. *United States v. Article Consisting of 36 Boxes, More or Less, Labeled "Line Away, Temporary Wrinkle Smoother, Coty"*, 415 F.2d 369, 371 (3d Cir. 1969) ("the fact that an article is a beautifying agent or 'cosmetic,' as is claimed here, does not preclude it[] also being a drug for purposes of the Act"); *see also* A2031.

Thus, courts have properly recognized that a drug's intended use should not be determined with blinders on but rather by consideration of *any and all* relevant evidence. The Ninth Circuit has specifically held that "intent may be derived or inferred from labeling, promotional material, advertising, or *any other relevant source*." *United States v. Storage Spaces Designated Nos. "8" & "49"*, 777 F.2d 1363, 1366 (9th Cir. 1985); *see also* 21 C.F.R. § 201.128 ("The intent is determined by such persons' expressions *or may be shown by the circumstances surrounding the distribution of the article*") (emphasis added).

Numerous courts have relied on a broad range of evidence under analogous FDCA provisions, including testimonials (*see United States v. Millpax, Inc.*, 313 F.2d 152, 154 (7th Cir. 1963)); facts surrounding product genesis and development, ingredients, and historical marketing practices (*see United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 574 (D.N.J. 2004)); actual use and knowledge thereof (*see United States v. 22 ... Finished Devices*, 714 F. Supp. 1159, 1165 (D. Utah 1989)); suggestive labeling and comparisons to established drugs (*see United States v. Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d 692, 699–700 (D. Md. 2001)); consumer use of the product (*see Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 74 (D.D.C. 2010)); and even "written material intended for the purpose of promoting a product, but never distribut-

ed" (*Kasz*, 855 F. Supp. at 541 n.6 (citing *United States v. An Article of Drug ... 47 Bottles*, 320 F.2d 564, 567–69 (3d Cir. 1963))).

Indeed, it is well established that "nothing limits the attempt to discern [objective] intent to labeling or advertising." *United States v. Travia*, 180 F. Supp. 2d 115, 119 (D.D.C. 2001); *see also United States v. Regenerative Scis., LLC*, 878 F. Supp. 2d 248, 256 (D.D.C. 2012) ("it is well established that the intended use of a product is determined from ... any … relevant source") (quotation omitted). The FDA itself has argued that "in determining a product's intended use, FDA is not limited to examining the product label." A3764–65; *see also id*. ("it is well established that the 'intended use' of a product ... is determined from *any ... relevant source*'"). This includes the types of "non-speech evidence" that Athena argues should be ignored (*see* AOB48–54), such as "product formulation and method of intake, actual use of the product ... and circumstances of sale." A3764–66 (collecting authority).

Accordingly, the district court had ample discretion to conclude that "intent may be derived or inferred from" a wide range of evidence, including "labeling claims, promotional material, advertising material, oral and written statements, evidence that the vendor is aware that his product is being offered or used by others for a purpose for which it is neither labeled nor advertised, *or any other relevant source*." A0030 (emphasis added).

Athena ignores this well-established law and cites no authority for its half-hearted argument that only the most "current" product labeling may be considered in determining intent. That argument makes no sense, as a copycat competitor like Athena could always avoid liability by changing its materials only after it gets called on the carpet. Certainly Athena has not shown any abuse of the district court's broad discretion in making evidentiary determinations regarding the importance of Athena's own documents, statements, and marketing program. As set forth below, the district court properly considered numerous indications of Athena's "intended use" for RevitaLash.

B. Summary Judgment for Allergan Was Proper

To identify a "genuine issue" of material fact, Athena "must do more than simply show that there is some metaphysical doubt as to the material facts"; rather, Athena "must come forward with *specific facts* showing that there is a genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574, 586–87 (1986) (internal quotations and citations omitted). Athena utterly failed to carry its burden in opposing Allergan's summary judgment motion.

The district court's lengthy opinion is amply supported by the record, including hundreds of pages of uncontroverted evidence establishing (among other things) that: (1) Athena created RevitaLash for eyelash growth; (2) Athena and its resellers promoted RevitaLash for eyelash growth; (3) Athena continually added

ingredients to RevitaLash that it believes cause eyelash growth; (4) consumers use RevitaLash for eyelash growth; and (5) Athena views Latisse, the only drug approved for eyelash growth, as a RevitaLash competitor.

Athena argues that "[t]here have been no claims about eyelash growth ... since June 2007" in either its labeling or any of its advertising. AOB44. But as set forth above, Athena and its resellers continued to promote RevitaLash specifically for eyelash growth well beyond 2007. *See supra* pp. 6–9 (and evidence cited therein). Athena also argues that "none of the [reseller] claims cited by either Allergan or the district court were made by authorized U.S. resellers" and thus "do not reflect Athena's objective intent." AOB47–48. This argument is also contradicted by the record, including a declaration from a RevitaLash reseller that "[a]ll content for RevitaLash Product advertisements on [the reseller's] website are approved by Athena." A1107–42, A0955–57; *see also V.E. Irons, Inc. v. United States*, 244 F.2d 34 (1st Cir. 1957) (in determining intended use the court is "entitled to utilize … representations made by … sales distributors"). In addition, Athena has waived these arguments by not making them below. *In re Mercury Interactive Corp. Sec. Litig.*, 618 F.3d 988, 992 (9th Cir. 2010).

Athena's argument that the district court failed to appreciate that Athena had "for many years ... sent a consistent, unequivocal message ... [that RevitaLash is] intended to beautify or improve eyelash appearance" and had "gone out of its way

to dispel any impression that Athena's products are intended for eyelash growth" is simply false. No evidence in the record shows or suggests that Athena actually *disclaimed* eyelash growth. *See*, *e.g.*, AOB44–45 ("[RevitaLash] is a cosmetic ... intended only to improve the appearance and enhance the beauty of your natural eyelashes .... If you have a medical condition associated with a loss of eyelashes, please consult your physician"). In fact, the district court properly concluded that even "the currently operative [RevitaLash] marketing, labeling and promotion taken in isolation from past efforts still show [Athena's] objective intent" that it grow eyelashes. A0032–33.

Athena's purported attempts to avoid using the word "growth," even had they been successful, could not create a genuine issue of material fact given the abundance of evidence demonstrating that RevitaLash is, and always has been, meant to grow eyelashes. Courts have uniformly rejected similar disclaimer arguments, including at the summary judgment stage. *See Millpax, Inc*., 313 F.2d at 154 (disclaimer ineffective where the overall circumstances demonstrated that the manufacturer intended product for use as a drug); *Storage Spaces Designated Nos. "8" & "49"*, 777 F.2d at 1366 n.5 ("[s]elf-serving labels cannot be allowed to mask the vendor's true intent as indicated by the overall circumstances"); *Kasz*, 855 F. Supp. at 543 ("It is apparent from even a cursory review ... that, despite their attempts to circumvent the requirements of the FDCA by avoiding direct hair

growth claims and by inserting disclaimer language in the literature, they in fact promote Solutions 109 for hair growth purposes"). The district court thus properly determined that "[Athena's] disclaimers made about the product not being a drug or used to cure disease are insufficient to create a genuine issue of fact about vendor intent." A0033 (citations omitted).

Athena continued to make overt growth claims even following the launch of its most recent prostaglandin formulation. For example, Athena continued to promote the product as "both dermatologist and ophthalmologist reviewed," and boasted that it had been proven effective "in only 3 weeks!" in a "clinical study." A0750; *see also* A0871. Its sales agents also continued to describe RevitaLash as an eyelash growth product in communications with customers. *See*, *e.g.*, A0865 ("My eyelashes now touch the inside of my glasses and are just so lush"), A0822 ("customers like to go on a maintenance program ... after you have the desired length that you want every day"), A0816 (discussing this "maintenance program"), A0838, A0850 (same, specifically identifying RevitaLash Advanced); *see also* A0869 ("Unlike other options that require a prescription, RevitaLash Advanced is affordable and offers very similar results .... My lashes were longer in just three weeks!"). And Athena's resellers continued to advertise that "RevitaLash® Advanced Eyelash Conditioner produces dramatically thicker, longer, and lusher lashes in 3 to 10 weeks" (A0960 (displaying before and after photos)), and "Revi-

taLash Advanced" is a "lash-beautifying serum to improve growth, fullness and thickness," A0969; *see also* A0956 ("No more extensions or false eyelashes. Now it's my own natural lashes!").[5]

Athena concedes on appeal that a product "is a drug" if it is "marketed ... to affect the structure of the human body (to affect eyelash growth)." AOB8. There can be no dispute that RevitaLash has been so marketed.

1. Athena's Intent Is Relevant in Determining Whether RevitaLash Is a "New Drug"

Athena's President and Rule 30(b)(6) designee testified that he: (1) conceived of RevitaLash after "treating" his wife with prostaglandin-based glaucoma drugs in order to regrow eyelashes lost as a result of chemotherapy; (2) informed Athena's first prostaglandin compound supplier that he intended the product for eyelash growth; (3) "had good reason to believe" that RevitaLash would "cause eyelashes to grow longer when [he] sold the first batch" in 2006 because it incorporated Bimatoprost; (4) changed the prostaglandin compound in RevitaLash in response to the FDA's seizure of a codefendant's product; and (5) believes that [redacted]

[5] Characterizing Athena's own claims as "misstatements" does not render them meaningless or inapplicable to summary judgment. AOB46; *see* A0032 n.13 ("Athena points to testimony that this was a misstatement .... However, it was stated more than just this instance .... Further, even as a misstatement, this shows possible underlying intent or conceptions of the product.").

[redacted] caused eyelash growth. A0670–72, A0677, A0680–81, A0684, A0687, A1537–39.

Athena argues that the district court erred in considering this testimony, but cites no authority for this proposition. Athena is bound by the testimony of its Rule 30(b)(6) witness. *Reilly v. NatWest Mkts. Grp., Inc.*, 181 F.3d 253, 268 (2d Cir. 1999) ("To satisfy Rule 30(b)(6), the corporate deponent has an affirmative duty to … give complete, knowledgeable and binding answers on its behalf"). As a result, the witness's testimony is not just his "subjective intent," as Athena claims. AOB51–52. Rather, it reflects the understanding of the corporation being sued.

Further, this testimony would be relevant even it if were only Athena's subjective intent. To be sure, courts are "not bound by [a] manufacturer's subjective claims of intent," but courts "can find true intent … based on objective evidence." *Kasz*, 855 F. Supp. at 543 (citing *Mathews*, 557 F.2d at 334). Indeed, the FDA's regulations—which have been incorporated wholesale into California law—specifically allow a finding of intended use based on "oral or written statements by such persons or their representatives." 21 C.F.R. § 201.128.

Accordingly, the fact that Athena admitted—through the binding testimony of its President, CEO, and Rule 30(b)(6) designee—to creating and developing Re-

vitaLash specifically to grow eyelashes can and should be considered in determining whether it intends RevitaLash to grow eyelashes.

2. RevitaLash's Effect of Growing Eyelashes Is Relevant and Was Properly Considered by the District Court

Athena also claims it was an abuse of discretion for the district court to consider the uncontroverted evidence that RevitaLash grows eyelashes based on the inclusion of various prostaglandin compounds, but again provides no authority for this restricted view of the evidence the district court could consider.

As described above, the California Health and Safety Code, by incorporating FDA regulations, allows the formulation of a product to inform its classification as a drug or a cosmetic. And the FDA further provides that "*[i]ngredients* ... may cause a product to be considered a drug because they have a well known (to the public and industry) therapeutic use." A2031. Thus, in a 2011 warning letter to a former defendant in this case, the FDA determined that "[p]rostaglandin analogs are well known to have an effect on the structure or function of the body" and "[t]he presence of the prostaglandin analog, isopropyl cloprostenate, along with appearance claims such as 'enhance the appearance of your lashes and brows,' 'fuller healthier-looking lashes,' ... indicate that products are intended to affect the structure or function of the body," rendering them "drugs" under the FDCA. A1036–37.

Athena's outdated authority does not require exclusion of actual product effects in determining the product's intended use. The Fourth Circuit in *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), did not, as Athena contends, "reject[] the argument that physical effects of tobacco products made them 'drugs.'" AOB49–50. Instead, the court held that the FDA lacked jurisdiction. 153 F.3d at 163, 176. The Supreme Court affirmed on this ground alone. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000). The other cases Athena cites are similarly inapposite and do not preclude courts from considering known effects when determining the intended use of a product. *See United States v. Articles of Drug ... Neptone*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,240 (N.D. Cal. Oct. 25, 1983) (speculating that future advertising changes "after some hiatus" *might* result in a different classification); *United States v. Articles of Drug ... "Helene Curtis Magic Secret"*, 331 F. Supp. 912, 915–17 (D. Md. 1971) (advertising determinative where product produced instant, temporary results); *United States v. An Article ... Line Away*, 415 F.2d 369, 371–72 (3d Cir. 1969) (same); *Mathews*, 557 F.2d at 336 (evidence of therapeutic use alone is insufficient for "drug" classification); *see also Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004) (ruling that the use of "product labeling ... as evidence of the sellers' intent" is constitutional).

The district court correctly determined that Athena's "authority does not stand for" the proposition that "physical properties of a product or the effect of a product on the body is not relevant to whether a product is a drug ...." A0030. These cases state only "that the determinative question is what the intended use is"; they do "not state that physical properties cannot be relevant to determining intent." *Id*.; *see also United States v. Livdahl*, 459 F. Supp. 2d 1255, 1260 (S.D. Fla. 2005) (evidence considered in determining intent should reflect the fact that the "FDCA is given a liberal interpretation to effectuate its high purpose of protecting unwary consumers in vital matters of health") (quotations and citations omitted). That Athena has *always* formulated RevitaLash with prostaglandin analogs it *believes* grow eyelashes is eminently relevant to whether it *intends* RevitaLash to grow eyelashes.

3. The District Court Properly Considered Athena's Six-Year RevitaLash Promotional Campaign

Athena's six-year promotional campaign is also relevant to Athena's intended use of RevitaLash, and the district court was correct in considering it. Athena is wrong that the district court should have essentially disregarded all but the most "current" RevitaLash labeling. AOB52–53.

Courts have repeatedly rejected the argument that past conduct bears no relevance to current intent. *See*, *e.g.*, *Lane Labs*, 324 F. Supp. 2d at 562, 569 (entering summary judgment based on intent demonstrated by actions conducted "over a

five year period"); *Kasz*, 855 F. Supp. at 535–38 (considering the circumstances surrounding the marketing of defendant's "shampoo" products throughout a several-year period); *see also Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 2 (D.D.C. 1989) (collecting authority).

Athena cites no competing authority, but rather relies on the fact that the FDA has not yet enjoined the sale of RevitaLash. AOB46–47. But "an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion," in part because an agency may believe a violation of law has occurred, but yet must determine "whether agency resources are best spent on this violation or another." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). This is particularly true of the overburdened FDA: "Over 8 billion personal care products, which include primarily cosmetics ... are sold annually in the United States." A1719. The FDA is "unable to take action immediately against all of these illegally marketed products." A2089. Like most regulatory agencies, the FDA "needs to make the best use of scarce Agency resources" as each enforcement "action[] is time consuming and resource intensive." *Id*. Thus, to accept Athena's argument that the FDA approved RevitaLash

by *inaction* would improperly conflate the type of justifiable inferences allowed at summary judgment with rampant speculation. A0033–34.[6]

Fundamentally, it would make no sense to adopt Athena's suggestion that the court should restrict its view to the most current RevitaLash formulation, completely divorced from its six-year history and the substantial demand created from Athena's past marketing and distribution. Athena has not materially altered the RevitaLash product or its marketing. Indeed, Athena advertises that each reformulation *enhances* the product's original purpose. *See*, *e.g.*, A0878 ("Periodically, Athena may make changes to the formula in order to ... *improve* their intended use") (emphasis added), A0764 ([redacted]), A0792 ("Periodically, we may make changes to the formula in order to improve its eyelash beautification function"), A0955 (reseller website) ("New Improved Formula! The amazing Revitalash, even better!!"). The combination of information and materials Athena gave to the public—labels, instructions for use, testimonials, marketing, and statements on the time the product takes to work—leave no doubt in the minds of consumers that RevitaLash

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[6] The California Department of Health Services is perhaps even more constrained. The California Drug, Medical Device and Consumer Product Safety Section—responsible for inspecting pharmaceutical and cosmetic manufacturers in California—has only 60 employees and enforcement is listed sixth out of ten essential services. A2100, A2103.

is intended to grow lashes. Athena offers no explanation for how, in light of these factors, RevitaLash could cause eyelashes to "appear" longer without actually growing lashes.

The district court thus properly refused to ignore previous iterations of Athena's marketing materials. A0031 ("Here all of the products begin with the word 'RevitaLash,' are similarly applied, have been introduced to replace the other, and Athena states the formula changes … make it work better"). In determining whether RevitaLash is intended to grow eyelashes, the fact that the product has been promoted—from day one—to do just that is highly relevant.[7]

III. The District Court Did Not Abuse Its Discretion in Issuing a Nationwide, Permanent Injunction

A district court's "decision to grant or deny permanent injunctive relief is an act of equitable discretion," which turns on four factors: (1) whether the plaintiff has suffered an irreparable injury; (2) whether remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) whether an equitable remedy is warranted considering the balance of hardships between the

[7] The Court should not consider Athena's improperly filed purported expert declarations. A2205, A2209, A2992. Allergan objected to, and filed a motion to strike, these declarations. A2246–56, A3162–83. The district court denied as moot Allergan's motion to strike, but noted the declarations "do appear to be primarily legal argument." A0039.

plaintiff and defendant; and (4) whether an injunction would disserve the public interest. *eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006). Under California's UCL, a court has "extraordinarily broad" authority to craft a remedy adequate to prevent the unfair competition and unfair business practices from reoccurring. *People v. Murrison*, 101 Cal. App. 4th 349, 364–65 (2002) ("Injunctive relief 'may be as wide and diversified as the means employed in perpetration of the wrongdoing'") (quoting *Hewlett v. Squaw Valley Ski Corp.*, 54 Cal. App. 4th 499, 540 (1997)).

Courts regularly enjoin the sale and distribution of unapproved and misbranded drugs. *See*, *e.g.*, *United States v. Kasz Enters., Inc.*, 862 F. Supp. 717, 722–23 (D.R.I. 1994); *Lane Labs*, 324 F. Supp. 2d at 575. Because Athena has not shown that the district court abused its discretion here, this Court should affirm the permanent injunction entered by the district court.

A. Athena's Unlawful Conduct Has Irreparably Harmed Allergan

In permanently enjoining Athena's unlawful conduct, the district court expressly found that: (1) Athena directly competes against Allergan in the eyelash growth product market; (2) Athena's sales cause Allergan to lose sales, goodwill, and market share; (3) Allergan would face a continued loss of prospective customers and competitive advantage if Athena were allowed to continue selling and marketing RevitaLash; and (4) Athena's presence on the market encourages other

companies to illegally enter the over-the-counter eyelash growth product market, further eroding Allergan's business. A0026, A0034, A0051–52. These findings amply satisfy the "irreparable harm" prong of the *eBay* standard.

Loss of sales, prospective customers, market share, and goodwill constitute irreparable harm. *See*, *e.g.*, *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 2013 WL 2158423, at *5–9 (Fed. Cir. May 21, 2013) (reversing district court's denial of permanent injunction against patent infringer); *Stuhlbarg Int'l Sales Co. v. John D. Brush & Co.*, 240 F.3d 832, 841 (9th Cir. 2001) ("Evidence of threatened loss of prospective customers or goodwill certainly supports a finding of the possibility of irreparable harm"); *see also Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) ("Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm"). As part of the *eBay* analysis "it is [also] proper for a district court to consider *past* harm to ... market share, revenues, and brand recognition [when] determining whether the [plaintiff] 'has suffered an irreparable injury.'" *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 449 F. App'x 923, 932 (Fed. Cir. 2011).

Similarly, given that market competitors necessarily gain or lose sales and market share at the expense of one another, "[d]irect competition in the same market is certainly one factor suggesting strongly the potential for irreparable harm." *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363

(Fed. Cir. 2012) (reversing district court's refusal to enter a permanent injunction against patent infringer when "the record shows that [the parties] were competing for the same customers in the same markets"); *see also Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1306 (Fed. Cir. 2012) ("As to irreparable harm, ... introduction of [a competing product] would result in considerable lost market share and price erosion"); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1152–57 (Fed. Cir. 2011) (district court abused its discretion in finding no irreparable injury where parties were in direct competition and plaintiff had lost market share).

The district court's factual findings clearly meet the foregoing standard. As Athena acknowledges, Allergan and Athena are "competitors" in the "market for eyelash enhancement products" by virtue of the sale of what Athena considers "reasonably interchangeable" products: Latisse and RevitaLash. A0417–21 (alleging counterclaims *based* on the products' competition); *see also* A0823–25, A0885–901 (demonstrating Athena's comparison of RevitaLash to Latisse in product marketing), A1543 (admitting it "views Latisse and RevitaLash as competing products").

Given the substitutable nature of RevitaLash and Latisse—both are clear liquids containing prostaglandins, which are marketed and sold to the same customers, and grow eyelashes when applied once a day to the skin (not the eyelashes) over a period of several weeks (*compare* A0750, A0988, *with* A1244)—it is hardly

surprising that customers in the market for eyelash growth products would try RevitaLash, which is less expensive and does not require a prescription. A1478–87 ([redacted]); *see also*, *e.g.*, A0417–21, A0899 ([redacted]), A1543.

Consumers have purchased over [redacted] worth of RevitaLash at the expense of Allegan's sales of Latisse, thereby reducing Allergan's share of the eyelash growth product market, and damaging its goodwill. A2624–31, A1542–43.

Athena's attempt to undermine Allergan's evidence that consumers were willing to choose RevitaLash over Latisse because that evidence relates to RevitaLash, not RevitaLash *Advanced*, fails. AOB57. As the district court found in entering summary judgment, Athena's attempt to rely on "changes to the formulation and name of its eyelash product over time … is unconvincing. Here all the products begin with the word 'RevitaLash,' are similarly applied, have been introduced to replace the other, and Athena states [that] the formula changes … make it work better." A0031.

All of the cases on which Athena relies hold only that it is improper to *presume* irreparable harm based *solely* on showing of likelihood of success on the

merits. AOB55–57. Indeed, the principal case on which Athena relies—*Ortho Pharmaceutical Corp. v. Cosprophar, Inc.*, 32 F.3d 690 (2d Cir. 1994)—is wholly inapposite, as it involves the question of whether harm should be presumed under the Lanham Act. *Id.* at 694. In addition, the Second Circuit left undisturbed the district court's finding that a plaintiff may "show that [its] sales are affected by the defendant's sales" by providing evidence that "people who buy [one] product are aware that [the other] product is an option." *Id.* at 695.

This principle has no application here, where the district court did not *presume*, but rather correctly *found* that Allergan suffered irreparable harm. These well-grounded findings were based on a wealth of evidence showing that Allergan and Athena are "direct competitors," that "Allergan ... lost sales, los[t] competitive advantage, and lost goodwill" due to Athena's introduction of a competing product into the market, and that Allergan would face a continued threatened loss of prospective customers "[i]f [Athena is] allowed to continue selling [and marketing RevitaLash]," including through the resulting "encourage[ment of] others to do the same." A0051–52; *see also* A0026 ("[Athena's] resellers and sales representatives sent emails ... discussing ways to market the product over ... Latisse in particular"), A0034 ("Athena is a competitor of Allergan's and … RevitaLash products specifically compete with Latisse, establishing injury in fact as pled"). Accordingly, this Court should affirm the district court's findings and conclusions.

B. The Injunction Is Appropriately Tailored to Remedy Allergan's Harm

The "district court has substantial discretion in defining the terms of an injunction and appellate review is correspondingly narrow." *Coca-Cola Co. v. Overland, Inc.*, 692 F.2d 1250, 1256 n.16 (9th Cir. 1982) (citation omitted). Here, the district court's injunction was narrowly tailored to the specific injury Allergan suffered as a result of Athena's unlawful sale of unapproved eyelash growth products. Although "an injunction should be 'tailored to eliminate only the specific harm alleged,' ... it should not be 'so narrow as to invite easy evasion.'" *Skydive Ariz., Inc. v. Quattrocchi*, 673 F.3d 1105, 1116 (9th Cir. 2012) (quoting *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 193 (1949)). As the district court found, any less restrictive injunction here would have failed to remedy Allergan's successfully adjudicated UCL claim in light of Athena's demonstrated willingness to frustrate enforcement through meaningless changes in its marketing and compound structure. A0052 ("Not granting an injunction would allow [Athena] to continue to cause irreparable harm to Allergan due to lost sales, loss of a competitive advantage, and lost goodwill"), A0045 ("there is no practical way to voluntarily limit sales and marketing in California absent a nationwide injunction"), *id.* ("changing the marketing [and not the sale of RevitaLash] would not necessarily mean that [RevitaLash is] not a drug[]" in light of "the nationwide demand cultivated by

[Athena]" and therefore "the[] sale would continue to violate the UCL absent regulatory approval").

The evidence before the district court demonstrated that Athena continued to sell RevitaLash to consumers nationwide—including in California—even *after* the court had adjudged such conduct unlawful, and even after Athena's CEO filed a declaration representing that Athena had "voluntarily discontinued all sales and promotion of its RevitaLash® Advanced eyelash conditioner in the United States and its territories." A2238, A2728–34. Any narrower injunction would have ignored this evidence and would have "invite[d] easy evasion" and thus failed to protect Allergan against continuing injury. *Skydive*, 673 F.3d at 1116.

Athena argues that the district court could have "restrained Athena only from ... marketing" RevitaLash "for eyelash growth," and not prohibited its sale. AOB62. But such an injunction would not have fully remedied Athena's violation of the UCL, because Athena "unlawfully marketed, *sold*, and distributed hair and eyelash growth products." A0019 (emphasis added); *see also* A0023 ("Athena has produced, marketed, and *sold* several compounds that are called at least in part RevitaLash") (emphasis added), A0028 ("any product considered a new drug that is *sold* without an approved new drug application is misbranded for purposes of Cal Health and Safety Code §§ 110398, 111440") (emphasis added). Indeed, in determining objective intent under the California Health and Safety Code, "a vendor's

objective intent in promoting, distributing, and *selling* the product is the key consideration." A0029 (emphasis added) (citing *Storage Spaces*, 777 F.2d at 1366). Thus, the district court appropriately and necessarily enjoined sales to remedy Athena's violation of the UCL through "selling misbranded products."

Further, an injunction limited to the marketing of RevitaLash would be meaningless in light of "the nationwide demand cultivated" by Athena through its years of unlawful promotion and advertising, and the fact that "the consequences of past promotional activities ... will linger for an unknown period of time into the future." A0045 ("This is especially true given consumer awareness about the products' use and effects; the nationwide demand cultivated by [Athena] and [its] resellers, distributors, and affiliates; and [Athena's] decision not to remove prostaglandin from the products"); *see also Kasz*, 862 F. Supp. at 722 ("defendants, if not appropriately enjoined, will profit from their past illegal activity").

Calling Athena's product a "cosmetic" changes nothing: The product remains a clear liquid intended to be applied to the base of the eyelid to grow eyelashes. An injunction directed only to current marketing claims would not account for the reality created by years of drug claims, and the failure by Athena to offer an explanation for how RevitaLash can cause eyelashes to "appear" longer without actually causing them to grow. The only adequate remedy for Athena's years of unlawful promotion of its products is to remove them from the market, unless and

until Athena obtains regulatory approval for the sale of such products, just as Allergan has done. *See Lemon v. Kurtzman*, 411 U.S. 192, 200–01 (1973) ("equitable remedies are a special blend of what is necessary, what is fair, and what is workable"); Restatement (Third) of Unfair Competition § 44(2)(h) (noting "the practicality of framing and enforcing the injunction" is a "primary factor[]" in fashioning injunctive relief).

Finally, Athena's argument that "lawful conduct may not be enjoined" is a red herring. AOB62. Athena identifies no lawful conduct that the injunction prohibits.

The injunction does not "forever bar" Athena from selling *any* product containing a prostaglandin analog; rather it is tailored to restrict *only* those prostaglandin products that Athena "market[s], promote[s] or otherwise direct[s] for application directly or adjacent to the eyelid or eyelash" (A0054), all of which the court has already properly adjudicated to be illegal unapproved drugs, regardless of whether Athena changes the product name. A0031; *see also Kasz*, 862 F. Supp. at 723 (enjoining the sale and marketing of "similar products" to ensure effective relief). Athena may request modification of the injunction to permit it to sell even a prostaglandin-based product applied to the eyelid or eyelash and called RevitaLash so long as it first secures regulatory approval. A0052 (noting that the injunction "will be lifted upon regulatory approval of the products as drugs").

Even if the injunction incidentally reached some lawful conduct, which it does not, Athena would not be entitled to reversal. "A federal court's equity jurisdiction affords it the power to enjoin otherwise lawful activity when necessary and appropriate in the public interest to correct or dissipate the evil effects of past unlawful conduct." *United States v. Holtzman*, 762 F.2d 720, 724 (9th Cir. 1985) (citing *Ford Motor Co. v. United States*, 405 U.S. 562, 573 & n.8 (1972)); *see also United States v. An Article of Drug*, 661 F.2d 742, 746–47 (9th Cir. 1981) (injunction prohibiting some legal conduct not overbroad because "an injunction may be framed to bar future violations that are likely to occur").[8]

C. The Injunction Is Not Geographically Overbroad

Athena argues that application of the injunction beyond California's borders violates the Commerce Clause and principles of comity. AOB58–61. But as the district court correctly held, "there is no practical way to voluntarily limit sales and marketing in California absent a nationwide injunction" because Athena had *already* cultivated a nationwide demand for its unapproved new drug, and the prod-

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[8] Contrary to Athena's argument (AOB62–63), the injunction does not violate the First Amendment. Athena did not "raise[] sufficiently for the trial court to rule on," and thus waived, this argument. *Mercury*, 618 F.3d at 992. And Athena is not being punished for speaking; rather, the injunction is an appropriate remedy for Athena's failure to secure required regulatory approval before putting its product on the market. The court adjudicated RevitaLash an illegal good, and the First Amendment thus poses no bar to enjoining its continued sale.

uct would make its way into California via Internet sales or through California re-sellers, and would continue to be marketed and advertised to California consumers. A0045. And in any event, as the district court also noted, Athena provided no evidence that any other state would permit Athena's unlawful conduct. A0046. This "conduct ... results in injury in California" (A0046), and is therefore properly enjoined under the UCL.

Nationwide injunctions for violation of state law are not uncommon. *See*, *e.g.*, *Carson v. Here's Johnny Portable Toilets, Inc.*, 810 F.2d 104, 105–06 (6th Cir. 1987) (issuing nationwide injunction for violation of Michigan state law); *see also United States v. AMC Entm't, Inc.*, 549 F.3d 760, 770 (9th Cir. 2008) ("Once a court has obtained personal jurisdiction over a defendant, the court has the power to enforce the terms of the injunction outside the territorial jurisdiction of the court, including issuing a nationwide injunction") (citing *Steele v. Bulova Watch Co.*, 344 U.S. 280, 289 (1952)).

California courts have long recognized that a plaintiff is entitled to an injunction against out-of-state conduct causing in-state injury under the UCL. *Norwest Mortg., Inc. v. Superior Court*, 72 Cal. App. 4th 214, 222–23 (1999) ("the 1992 amendment … eliminated any linguistic basis for a defendant to contend that … [the UCL] prohibited an injunction against out-of-state conduct"); *see also Yu v. Signet Bank*, 69 Cal. App. 4th 1377, 1391 (1999) ("a defendant who is subject to

jurisdiction in California and who engages in out-of-state conduct that injures a California resident may be held liable for such conduct in a California court"). Contrary to Athena's assertion, *Sullivan v. Oracle Corp.*, 51 Cal. 4th 1191 (2011), did not alter California law that the UCL permits an injunction against "wrongful conduct that occurs out-of-state but results in injury in California." *Speyer v. Avis Rent a Car Sys., Inc.*, 415 F. Supp. 2d 1090, 1099 (S.D. Cal. 2005); *see also Norwest*, 72 Cal. App. 4th at 224 n.12 ("the scope of injunctive relief available to a plaintiff who was already entitled to pursue a claim under the UCL … [includes] out-of-state conduct causing injury within the state"). *Sullivan* involved claims of *out-of-state* injury to nonresident plaintiffs (51 Cal. 4th at 1209) and thus has no bearing on this case, whereas Allergan—a California resident—suffers injury in California. *See* A0047 (holding that "the injury the Court is addressing ... affects Allergan in California").[9]

Nor does the Commerce Clause pose a bar to the nationwide scope of this injunction. "The Supreme Court's current dormant Commerce Clause jurisprudence is concerned with preventing economic protectionism and inconsistent regulation," neither of which is implicated by the injunction in this case. *IMS Health*

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[9] *Sajfr v. BBG Commc'ns, Inc.*, 2012 WL 398991, at *13–14 (S.D. Cal. Jan. 10, 2012), another case on which Athena inappropriately relies, is even further removed—involving injury that occurred solely in a foreign country.

Inc. v. Mills, 616 F.3d 7, 25 (1st Cir. 2010), *vacated on other grounds sub nom. IMS Health Inc. v. Schneider*, 131 S. Ct. 3091 (2011). Indeed, "it is inevitable that a state's law ... will have extraterritorial effects [and] [t]he Supreme Court has never suggested that the dormant Commerce Clause requires Balkanization, with each state's law stopping at the border." *Instructional Sys., Inc. v. Computer Curriculum Corp.*, 35 F.3d 813, 825–26 (3d Cir. 1994) (reversing district court's determination that enjoining out-of-state conduct would violate the Commerce Clause); *see also IMS Health*, 616 F.3d at 30–31 n.29 (the Commerce Clause "has never meant that states are powerless to regulate all transactions beyond their borders").

Extraterritorial application of state law thus implicates the Commerce Clause under the *Edgar v. MITE Corp.*, 457 U.S. 624 (1982), line of cases only when it has the "practical effect" of "impos[ing] inconsistent obligations" on a party due to a conflict with another state's law. *Pac. Merchant Shipping Ass'n v. Goldstene*, 639 F.3d 1154, 1178 (9th Cir. 2011). Athena must (but cannot) show that compliance with the terms of the injunction would subject it to "inconsistent obligations" due to an "actual conflict among state regulations." *Id.*; *see also Instructional Sys.*, 35 F.3d at 826; *S.D. Myers, Inc. v. City & Cnty. of S.F.*, 253 F.3d 461, 470 (9th Cir. 2001) ("the [Supreme] Court has never invalidated a state or local law under the dormant Commerce Clause based upon mere speculation about the possibility of conflicting legislation"); *Cf. also CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S.

69, 88–89 (1987) (Commerce Clause not implicated where the statute in question did "not create an impermissible risk of inconsistent regulation by different States").[10]

Athena has not even attempted to do this. As noted above, many states impose the same requirements as California's Health and Safety Code. And even those states which have not adopted their own laws *cannot* enact a law that differs from the FDCA. Indeed, because the FDCA sets a regulatory floor, Athena could *never* demonstrate contrary state legislation. *See Wyeth*, 555 U.S. at 577–81; *Chavez v. Blue Sky Natural Beverage Co.*, 268 F.R.D. 365, 375 (N.D. Cal. 2010) (finding that federal regulations act as a floor and set minimum standards); A0046 ("Defendants do not demonstrate that there would be a conflict with other states' laws, and there is no reason to believe that other states would permit Defendants' conduct").

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[10] Athena cites only *Shearson Lehman Bros. Inc. v. Greenberg*, 1995 WL 392028 (9th Cir. July 3, 1995)—an unpublished and non-precedential opinion, which "may not be cited to the federal courts in the Ninth Circuit," or in this Court. 9th Cir. R. 36–3; Fed. Cir. R. 32.1(d). *Shearson* has also been recognized as "particularly unpersuasive authority," in light of its failure to "address recent California case law" or to offer any reasoning or analysis leading to its conclusion. *Roskind v. Morgan Stanley Dean Witter & Co.*, 80 Cal. App. 4th 345, 355 (2000).

Lastly, Athena's statement that the district court "invoked the doctrine of comity" "to justify its nationwide injunction" and to "circumvent" a nonexistent "limitation on its [authority]" is incorrect. AOB59. One of Athena's co-defendants argued below that a nationwide injunction would violate principles of comity. A3824–25. In response to that argument, the court concluded that a nationwide injunction "would not ... offend comity" because no state's laws conflict with the California Health and Safety Code provisions at issue, and therefore the injunction could not "affront the sovereignty or law of another state." A0049. That is entirely correct.

Athena has pointed to no state in which the advertising and sale of an unapproved drug would be legal, as it must do to invoke the comity doctrine. *See AMC Entm't, Inc.*, 549 F.3d at 773 (comity limits the nationwide scope of injunctive relief only when there is "direct conflict" between state laws); *Las Palmas Food Co. v. Ramirez & Feraud Chili Co.*, 146 F. Supp. 594, 602 (S.D. Cal. 1956), *adopted and summarily aff'd*, 245 F.2d 874 (9th Cir. 1957) (rejecting comity argument in injunction context absent evidence of any actual "interference with" the law of another jurisdiction).

Nor has Athena pointed to any authority to support its contention that "regardless of the substantive enactments" of the other 49 states, "the will of the Tennessee legislature" is offended because the Tennessee State Commission is the en-

tity tasked with enforcing that state's food and drug laws. AOB60. Tellingly, Athena does not dispute that the sale of its drugs in Tennessee is against the law. Athena has thus failed to meet its burden of showing the comity doctrine is applicable. *Int'l Nutrition Co. v. Horphag Research Ltd.*, 257 F.3d 1324, 1329 (Fed. Cir. 2001) (party asserting the comity doctrine bears the burden of proof); *see also Marsoner v. United States*, 40 F.3d 959, 964 (9th Cir. 1994) (same). Athena's illegal actions in this case are illegal everywhere, and comity is thus not offended by prohibiting them.

CONCLUSION

The final judgment and order of permanent injunction entered by the district court should be affirmed.

Dated: June 27, 2013 Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Mark A. Perry, hereby certify that on June 27, 2013, a true and correct copy of the Principal Brief for Allergan, Inc. – Confidential Version was electronically filed with the Clerk of the Court using CM/ECF and was served on the following counsel via electronic mail, and that two true copies of the foregoing document will be served via third-party commercial carrier for next-day delivery on the following counsel within five days of the court's acceptance of the document:

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